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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT

PAPER NUMBER

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
**09/479,145**

Applicant(s)  
**Weinstein**

Examiner  
**S. Devi, Ph.D.**

Group Art Unit  
**1641**



☒ Responsive to communication(s) filed on 02/29/2000.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-32 ☒ is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) \_\_\_\_\_ is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-32 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All ☐ Some\* ☐ None ☐ of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received:

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Art Unit: 1641

### Restriction / Election

1) Claims 1-32 are under prosecution.

**2) Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your election responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

3) Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, 14-23 and 28, drawn to an isolated nucleic acid encoding Opal, a vector comprising the same and a host cell comprising the vector, classified in class 536, subclass 23.1.
- II. Claims 8-13 and 29, drawn to a purified Opal protein and a composition comprising the same, classified in class 530, subclass 350.
- III. Claim 24, drawn to a method of making Opal protein by maintaining a host cell comprising a nucleic acid encoding Opal, classified in class 435, subclass 69.3 and class 935, subclass 71.
- IV. Claims 25-27, drawn to a method of inducing growth or regeneration of nervous tissue by administering Opal protein to said tissue, classified in class 435, subclass 375.
- V. Claim 30, drawn to a method for inducing growth or regeneration of nervous tissue comprising contacting the nervous tissue with a modulator of Opal expression, classified in class 435, subclass 375.
- VI. Claim 31, drawn to a method for providing biologically active Opal to the cell of

with an expression vector and transplanting into the individual, classified in class 424, subclass 9.2.

- VII. Claim 32, drawn to a method for evaluating an agent that may induce nervous tissue growth or regeneration comprising contacting a candidate agent with nervous tissue and detecting the level of Opa1 expressed in the nervous tissue, classified in class 436, subclass 815.

4) Inventions I-VII are distinct from one another. Inventions I and II are drawn to distinct products: a nucleic acid and a protein. These products are distinct from one another structurally, physicochemically, functionally, immunologically and/or biologically.

Inventions III, IV, V, VI and VII are directed to independent and distinct methods, which differ from one another in method steps, parameters and reagents or compositions used, and ultimate goals accomplished. The method of making a Opa1 protein is unrelated to the method of inducing growth or regeneration of nervous tissue, the method for providing biologically active Opa1 to the cell of an individual and the method for evaluating an agent that may induce nervous tissue growth or regeneration.

Although the methods of inventions IV and V belong to the same class/subclass, the methods involve different steps and/or use different products.

Inventions III and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P 806.05(f)). In the instant case, the Opa1 protein of invention II can be made by a process materially different from the process of invention III, without using the host cell, for example, by chemical synthesis.

Invention II, and inventions IV and VI, are related as product and process of using the product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process of using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of

the Opa1 protein of invention II can be

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used in a materially different process, for example, as a source of coating antigen in an *in vitro* diagnostic assay.

Inventions I and II are unrelated to inventions V and VII, because the products of inventions I and II are not required to practice the methods of inventions V and VII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification/subclassification and divergent subject matter, and since a search performed for one would not be co-extensive for the other, restriction for examination purposes as indicated is proper.

- 5) Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).
- 6) Applicants are reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filled petition under C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).
- 7) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. The Examiner can normally be reached on Monday to Friday from 7.45 a.m. to 4.15 p.m. A telephone message may be left on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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# RESTRICTION ELECTION FACSIMILE TRANSMISSION

DATE:

FROM/ATTORNEY:

FIRM:

PAGES, INCLUDING COVERSHEET:

PHONE NUMBER:

TO EXAMINER: Dr. S. Devi

ART UNIT: 1641

SERIAL NUMBER:

FAX/TELECOPIER NUMBER: (703) 305-3704

**PLEASE NOTE: THIS FACSIMILE NUMBER IS TO BE USED ONLY  
FOR RESPONSES TO RESTRICTIONS.**

COMMENTS: \_\_\_\_\_  
\_\_\_\_\_  
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IF YOU HAVE NOT RECEIVED ALL THE PAGES OF THIS TRANSMISSION, PLEASE CONTACT THE ATTORNEY AT THE TELEPHONE NUMBER LISTED ABOVE.

IN COMPLIANCE WITH 1096 OQ 30, THE FILING DATE ACCORDED EACH OFFICIAL FAX TRANSMISSION WILL BE DETERMINED BY THE FAX MACHINE DATE STAMP FOUND ON THE LAST PAGE OF THE TRANSMISSION, UNLESS THAT DATE IS A SATURDAY, SUNDAY, OR FEDERAL HOLIDAY WITHIN THE DISTRICT OF COLUMBIA, IN WHICH CASE THE OFFICIAL DATE OF RECEIPT WILL BE THE NEXT BUSINESS DAY.

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